



General

Guideline Title

Prevention of unintentionally retained foreign objects during vaginal deliveries. Health care protocol.

Bibliographic Source(s)

Institute for Clinical Systems Improvement (ICSI). Prevention of unintentionally retained foreign objects during vaginal deliveries. Health care protocol. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2012 Jan. 34 p. [24 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Institute for Clinical Systems Improvement (ICSI). Prevention of unintentionally retained foreign objects during vaginal deliveries. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2009 Nov. 30 p. [24 references]

Recommendations

Major Recommendations

Note from the National Guideline Clearinghouse (NGC) and the Institute for Clinical Systems Improvement (ICSI): For a description of what has changed since the previous version of this protocol, refer to [Summary of Changes Report– January 2012](#) .

The recommendations for prevention of unintentionally retained foreign objects during vaginal deliveries are presented in the form of a protocol and an algorithm with 13 components, accompanied by detailed annotations. An algorithm is provided in the [original guideline document](#) for Prevention of Unintentionally Retained Foreign Objects during Vaginal Deliveries. Clinical highlights and selected annotations (numbered to correspond with the algorithm) follow.

Class of evidence (A-D, M, R, X) definitions are provided at the end of the "Major Recommendations" field.

Clinical Highlights

- Sponges/soft goods, sharps and miscellaneous items will be counted for vaginal deliveries. (*Annotation #3, Aim #1*)
- Sponges/soft goods with radiopaque markers are the only soft goods that will be present on the delivery field. (*Annotation #3, Aim #1*)
- Establishing accurate count processes for the baseline and final counts are all critical steps in preventing an unintentionally retained intra-delivery foreign object during vaginal deliveries. If the baseline count is not accurately performed before using any countable items, all subsequent counts should be considered compromised. For compromised and unreconciled counts, a radiograph shall be obtained to ensure that a foreign object has not been unintentionally retained. (*Annotation #3, 6, 10, 12; Aim #1*)
- Good communication is necessary before and during the procedure, when staff changes and/or at hand-offs (e.g., transitioning to the

operating room). (*Annotation #3, Aim #1*)

Special Considerations

- Temporary Packing of the Genital Tract After a Vaginal Delivery and Beyond the Immediate Recovery Period – When the genital tract is packed post-delivery and the packing is intentionally kept in place beyond the immediate recovery period (one to two hours after delivery), the risk for an unintentionally retained foreign object increases. Strict adherence to the count process and documentation and communication of all packed materials, and reliable implementation of procedures to ensure removal of packing prior to discharge are important for the prevention of an unintentionally retained item. Imaging is recommended only when the final count cannot be reconciled.
- Equipment Components – It is important to conduct an examination of all equipment used during the vaginal delivery to ensure that the equipment is intact and no incidental pieces and instruments are retained.

Labor and Delivery Retained Foreign Objects Prevention Protocol Annotations

The counting recommendations outlined in this protocol are based on consensus statements and guidelines of American College of Obstetricians and Gynecologists and the American Academy of Pediatrics. In addition, articles on communication, teamwork, multitasking and interruptions and their relationship to unanticipated events were referenced. This protocol has identified staff responsible for various steps based on their scope of practice and licensing requirements. Direct and explicit language (e.g., will, must) has been incorporated to reduce variation and to identify the steps of the protocol where variation could significantly increase the risk for an unintentionally retained object [C], [D], [R], [NA].

Accurately accounting for all items that could potentially become unintentionally retained is a shared responsibility of the entire Labor and Delivery team. The ultimate responsibility for prevention of an unintentionally retained object lies with the provider performing the procedure.

1. Room Survey

A designated person performs a room survey to ensure that all evidence (e.g., count record, patient ID stickers) from the previous delivery has been removed. The room survey is completed before the next patient arrives in the room.

2. Open Applicable Pack in Anticipation of Vaginal Delivery

Ideally the pack should be opened only when it is known the pack will need to be utilized and immediately before use; however, the work group acknowledges that this may not be possible in all cases. As a result, facilities are encouraged to establish guidelines related to the amount of time a pack may be open prior to use in light of the following considerations:

- The need to keep the open pack in direct observation by staff at all times
- Direct correlation between the amount of time the pack is open and risk of infection

In order to reduce waste and cost, it is recommended that, whenever possible, facilities develop a process for opening items only when they are needed by the delivering provider.

Organizations may elect to have separate delivery packs for routine versus precipitous deliveries considering the variation with respect to these presentations. Additionally, it is recommended that facilities consider the financial and logistical benefits of eliminating countable items from the delivery pack.

3. Baseline Count – Count and Document All Countable Items in the Applicable Pack

The timing and frequency of the count process in Labor and Delivery are different from the process in the surgical suite. Frequently, countable items are not used during or after a delivery. Items that are not opened during the delivery do not need to be counted.

What Items Will Be Included in the Count Process

It is the work group's recommendation that all non-radiopaque items on the delivery tray or within the delivery field be counted. In addition, the following items will be counted:

Sponges/soft goods: Sponges and soft goods that require counting include such items as gauze pads, vaginal packs or laparotomy sponges used to absorb fluids, protect tissues or apply pressure or traction.

Only radiopaque sponges/soft goods will be present on the delivery tray or within the delivery field [R].

Sponges/soft goods will have visual verification that the radiographic-detectable indicator is present prior to being placed in the delivery field.

RayTec/laparotomy sponges will not be cut into pieces [R].

Radiopaque sponges/soft goods that are placed in the genital tract should have a detection "tail" that can be clipped to the patient's drapes

[R].

Sharps: Sharps that require counting include items with edges or points capable of cutting or puncturing such as suture needles and hypodermic needles [R].

Miscellaneous items: Miscellaneous items that must be either counted or accounted for include fetal scalp electrodes, intrauterine pressure catheters and non-radiopaque items such as umbilical tapes, vacuum sponges and other small items [R]. The internal fetal scalp electrode must be accounted for at the time of delivery. Should the patient have the electrode in place prior to delivery and it is still in place at the time of delivery, the nurse and provider should account for it along with the sponge count.

When the Count Process Will Be Performed [R]

- Immediately before the delivery tray is used (baseline count) [R].
- When countable items are added to the delivery field.
- At the end of the delivery:
 - For sharps, the final count will be performed at the end of the case by counting each sharp placed into a needle box by the provider.
 - For sponges/soft goods and miscellaneous items, the final count will be performed at the end of the procedure by counting each item that was placed into the designated basin [R]. Sponges/soft goods WILL NOT be placed in the container that is used to collect and manage body fluids during the delivery until after the final count has been performed and reconciled.
 - If the delivering provider is called away for an emergency, the final count will be completed by the Labor and Delivery nurse and a second person trained in the count process.
- Any time a member of the Labor and Delivery team has concerns about the accuracy of the count, even when the counts appear correct.
- Whenever there is a permanent staff change of the Labor and Delivery nurse.
 - All visible items will be counted and all items in use in the delivery field will be accounted for.

When a count is not required:

- If there is a permanent change in a member of the Labor and Delivery team other than the Labor and Delivery nurse. A structured hand-off is required but a count is not.
- When the Labor and Delivery nurse change is temporary (e.g., lunch break). A structured hand-off is required but a count is not.

How the Count Process Will Be Performed

- Two individuals, one of whom will be a registered nurse, will directly view and verbally count each item. These individuals must be trained in the counting process [R]. The second person may be another registered nurse, the provider, a Labor and Delivery technician, or a nursing assistant.
- Distractions and interruptions should be minimized during the count process [R]. If the count process is interrupted in a particular category (e.g., laparotomy sponges, sutures), the count of that particular category will start over.
- Any countable items, when opened, will be counted and documented prior to entering the delivery field.
- The Labor and Delivery nurse will document the number and type of sponges/soft goods, sharps, and miscellaneous items on the preformatted count sheet or whiteboard. The other person involved in the count process will confirm the number.
 - The work group does NOT recommend keeping two concurrent count records.
- Sponges/soft goods will be separated and counted individually [R].
- Every sponge/soft good will be visually inspected to verify that the radiographic-detectable indicator is present [R].
 - If the indicator is not present, the entire package of sponges/soft goods will be removed from the room and given to the designated person for follow-up with the manufacturer [R].
- When the labeling on the package does not match the number of items in the package, they will be removed from the room and given to the designated person for follow-up with the manufacturer [R].
- Sponges/soft goods used by anesthesia will not enter the delivery field or be mixed in with sponges/soft goods used and counted for the delivery process.

For specific information related to the final count, Refer to Annotation #10, "Final Count – Perform Final Count."

6. Count and Document All Countable Items Added to the Delivery Field at the Time They Are Added

If any additional countable items are added to the delivery field after the baseline count but before the final count, they will be counted in the same manner as the baseline count. Additional counted items will be added to the count on the count sheet or white board. Final count will

equal baseline counted items plus all added items.

Additional instructions regarding fetal scalp electrode documentation: Whenever a fetal scalp electrode is placed onto the fetal scalp, the person placing the fetal scalp electrode inspects it for structural integrity and completeness, and verbally announces its placement to the Labor and Delivery nurse. The Labor and Delivery nurse documents the fetal scalp electrode on the count worksheet. When the fetal scalp electrode is removed, the person removing it inspects it for structural integrity and completeness, and verbally announces its removal so the count worksheet can be updated appropriately.

*Note: When a fetal scalp electrode is removed from the fetal scalp, the Labor and Delivery nurse will draw a line across (i.e., cross out) the fetal scalp electrode on the count worksheet and will write "removed" following the entry.

Countable items: Any item that could be unintentionally left behind after a vaginal delivery and is subject to the count process. This includes:

- Miscellaneous items: Includes fetal scalp electrodes, intrauterine pressure catheters, non-radiopaque items such as umbilical tapes, vacuum sponges and other small items.
- Sharps: Items with edges or points capable of cutting or puncturing. In the context of a vaginal delivery, sharps include, but are not limited to, suture needles and hypodermic needles.
- Sponges: Soft goods such as gauze pads, vaginal packs or laparotomy sponges used to absorb fluids, protect tissues or apply pressure or traction.

8. Is Patient Moved Out of Labor Room?

Emergency Transfer to Surgery during or Immediately after a Vaginal Delivery – When a mother's and/or fetus's condition becomes critical during the delivery, or the mother's condition becomes critical immediately following a vaginal delivery and transfer to surgery is required, there may not be adequate time for staff to perform the final vaginal delivery count. In this situation, all counts are considered compromised and the mother is at increased risk for an unintentionally retained foreign object. If the mother's condition allows, imaging should be obtained prior to leaving the operating room to rule out the possibility of an unintentionally retained foreign object.

Any countable items used during the vaginal delivery that accompany the patient to surgery will need to be documented in the patient's record and verbally communicated to the surgical team.

If the transfer to surgery is not emergent, and there is time to perform and reconcile the vaginal delivery final count before the mother leaves the Labor and Delivery room, this is the preferred method. The subsequent surgical procedure is considered separately from the vaginal delivery procedure; therefore, the count process recommended for surgery is to be used.

10. Final Count – Perform Final Count

The final count should be performed before the provider leaves the room. If the delivering provider is called away for an emergency, the final count will be completed by two members of the Labor and Delivery team who have been trained in the counting process. One member of the final count team will be a registered nurse.

Final Count Process

- Used sharps will be counted at the end of the procedure by counting each sharp as the provider places it into a needle box.
- Used sponges/soft goods will be placed in the designated basin -- NOT in the container that is used to collect and manage body fluids during Labor and Delivery until after the final counts have been performed and reconciled.
- Used sponges/soft goods will be separated, unballied and/or pulled apart before counting to aid the count process.
- Sponges/soft goods will be counted at the end of the procedure [R].
- All sharps and miscellaneous items, such as fetal scalp electrodes, will be inspected for broken or missing pieces.
- Any items dropped during the procedure will be retrieved, shown to the person responsible for counting, and isolated from the delivery field.
- Any items intentionally left in a patient will be documented on the procedure record and communicated verbally to the next caregiver. The patient will also be informed.
- No sponges/soft goods, sharps or miscellaneous items will be removed from the Labor and Delivery area until all counts have been performed and reconciled [R].
- Countable items that accompany the infant out of the Labor and Delivery area will be communicated to the Labor and Delivery nurse and documented on the count sheet [R].
- After all counts have been reconciled, all delivery tray items will be removed from the Labor and Delivery area before setup begins for the next procedure.

For other counting information, refer to Annotation #3, "Baseline Count – Count and Document All Countable Items in the Applicable

Pack."

11. Able to Reconcile Count?

Reconciliation Process for a Count Discrepancy

When a discrepancy is identified, the Labor and Delivery nurse reports the number and type of missing items to the provider.

The following steps should be performed [R]:

- Make a visual inspection of the Labor and Delivery suite, including a visual inspection of the area surrounding the delivery field, the floor, linens, and trash receptacles.
- Repeat the count and verify that there is still a discrepancy. A discrepancy must never be resolved by using the number listed on opened packages.
- Special attention should be paid to items that can stick together, such as sponges/soft goods. Sponges/soft goods will be separated and unballied and/or pulled apart for counting.
- If the mother's condition permits, the genital tract should be explored, with special attention paid to the location of where that particular item may be retained [R].

If the counts cannot be reconciled:

- Post-delivery imaging should be obtained if counts cannot be reconciled [R].
 - The physician and/or radiologist should review the films before the end of the immediate recovery period (one to two hours). See Annotation # 12, "Obtain Radiographic Imaging for Potential Retained Foreign Object."

Unreconciled count:

- If the count cannot be reconciled after all the steps above are completed, attempts to reconcile the count and the outcomes of those attempts will be documented per the organization's policy.

12. Obtain Radiographic Imaging for Potential Retained Foreign Object

Portable radiographic imaging obtained in the Labor and Delivery room or a post-delivery image obtained in a radiographic room can be used to exclude the possibility of a retained foreign object. However, radiographic imaging is not a substitute for performing an accurate count process and a thorough genital tract exploration [R].

Portable radiographic imaging can be performed in the Labor and Delivery room and, if the retained item is identified and removed, allows reconciliation of a discrepancy before the patient is transferred to a new room. This added convenience, however, comes at a cost. Portable machines have lower power, which results in less penetration and thus poorer image quality. In addition, placement of the film cassette might be restricted with portable machines, and this could result in sub-optimal capture of the anatomic field.

The highest quality radiographic imaging is obtained in a radiographic room with fixed radiographic equipment and moving grid.

Radiographic imaging should be obtained when:

- Counts cannot be reconciled
- The patient's condition does not allow for the count process to be followed (rushed counts, incomplete counts)
- A member of the Labor and Delivery team has a concern about the accuracy of the count that cannot be resolved

Radiographic imaging in a room with fixed equipment and moving grid should be obtained when:

- The patient's condition did not allow for a portable radiographic image to be obtained
- The entire anatomic area could not be visualized on the portable radiographic image
- The portable radiographic image failed to locate the potentially retained foreign object and the count could not be reconciled

Radiographic imaging requests should include the following information:

- Callback number and clinician name (e.g., certified nurse midwife, collaborating physician)
- Location and status of patient (e.g., in post-delivery recovery, Caesarean room)
- Number and type of item missing
- Details of the delivery, as appropriate

Before a radiologist interprets the radiographic images:

- The radiology technologist will review the radiographic image for quality and repeat the imaging as necessary
- When available, a Labor and Delivery physician will review the radiographic image to check for adequate anatomic coverage of the

genital tract

If a retained foreign object is identified on an image, even prior to the formal read by the radiologist, the midwife or Labor and Delivery physician should attempt to retrieve the retained item. If the item is retrieved and this makes the count correct, no further action is needed except to document the events in the medical record.

If initial review does not reveal a retained foreign object, or the Labor and Delivery physician is not able to verify adequate anatomic coverage on a portable image, an image in a radiographic room with fixed equipment and moving grid should be obtained once the patient is stable for transport.

For a negative film with a discrepancy in the count, the work group recommends that the radiologist and Labor and Delivery physician simultaneously review the radiographic image, ensuring adequate anatomic coverage and adequate film quality before declaring the film negative.

The films should be reviewed before the end of the immediate recovery period (one to two hours).

If a radiologist is not immediately available, the preliminary interpretation of the radiographic images used to identify a potentially retained foreign object is the responsibility of a Labor and Delivery physician because interpretation of radiographic films generally falls outside the scope of practice of nurses and certified nurse midwives.

Final reporting of radiologic imaging results should be completed in accordance with appropriate state and federal requirements [R].

Definitions:

Classes of Research Reports

Class	Description
Primary Reports of New Data Collections	
A	Randomized, controlled trial
B	Cohort-study
C	Non-randomized trial with concurrent or historical controls <ul style="list-style-type: none">• Case-control study• Study of sensitivity and specificity of a diagnostic test• Population-based descriptive study
D	Cross-sectional study <ul style="list-style-type: none">• Case series• Case report
Reports that Synthesize or Reflect upon Collections of Primary Reports	
M	Meta-analysis <ul style="list-style-type: none">• Systematic review• Decision analysis• Cost-effectiveness analysis
R	Consensus statement <ul style="list-style-type: none">• Consensus report• Narrative review
X	Medical opinion

Clinical Algorithm(s)

A detailed and annotated clinical algorithm for prevention of unintentionally retained foreign objects during vaginal deliveries is provided in the [original guideline document](#) .

Scope

Disease/Condition(s)

Unintentional retention of foreign objects during vaginal delivery

Guideline Category

Prevention

Clinical Specialty

Nursing

Obstetrics and Gynecology

Preventive Medicine

Radiology

Surgery

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Health Care Providers

Health Plans

Hospitals

Managed Care Organizations

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To describe the necessary steps, which if implemented, should prevent the unintentional retention of foreign objects during vaginal delivery

Target Population

Patients who present with an anticipated vaginal delivery

Interventions and Practices Considered

1. Room survey to ensure all evidence from previous delivery has been removed
2. Opening applicable delivery pack in anticipation of vaginal delivery
3. Performing baseline count – counting and documenting all countable items in the delivery pack
4. Counting and documenting all countable items added to the delivery field at the time they are added
5. Considerations for emergency transfer during or after vaginal delivery
6. Performing final count
7. Reconciliation process for a count discrepancy
8. Obtaining radiographic imaging for potential retained foreign object

Major Outcomes Considered

Not stated

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

A literature search of clinical trials, meta-analyses, systematic reviews, or regulatory statements and other professional order sets and protocols is performed.

A consistent and defined process is used for literature search and review for the development and revision of Institute for Clinical Systems Improvement (ICSI) Protocols. Literature search terms for the current revision of this document include retained foreign objects and labor and delivery from May 2009 through June 2011.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Classes of Research Reports

Class	Description
Primary Reports of New Data Collections	
A	Randomized, controlled trial
B	Cohort-study
C	Non-randomized trial with concurrent or historical controls

Class	Description
	<ul style="list-style-type: none"> • Case-control study • Study of sensitivity and specificity of a diagnostic test • Population-based descriptive study
D	<p>Cross-sectional study</p> <ul style="list-style-type: none"> • Case series • Case report
Reports that Synthesize or Reflect upon Collections of Primary Reports	
M	<p>Meta-analysis</p> <ul style="list-style-type: none"> • Systematic review • Decision analysis • Cost-effectiveness analysis
R	<p>Consensus statement</p> <ul style="list-style-type: none"> • Consensus report • Narrative review
X	Medical opinion

Methods Used to Analyze the Evidence

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Document Development

A workgroup consisting of 6 to 12 members that includes physicians, nurses, pharmacists, other healthcare professionals relevant to the topic, and an Institute for Clinical Systems Improvement (ICSI) staff facilitator develops each document. Ordinarily, one of the physicians will be the leader. Most work group members are recruited from ICSI member organizations, but if there is expertise not represented by ICSI members, 1 or 2 members may be recruited from medical groups, hospitals or other organizations that are not members of ICSI.

The work group will meet for 3 to 4 three-hour meetings to develop the protocol. Under the coordination of the ICSI staff facilitator, the work group develops the algorithm and writes the annotations and literature citations. The literature is graded in the document based on the ICSI Evidence Grading System.

Once the final draft copy of the protocol is developed, the document is sent to the ICSI members for review and comment.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Review and Comment

The purpose of the review and comment process is to provide an opportunity for the clinicians in the member organizations to review the science behind the recommendations and focus on the content of the protocol. Review and comment also provide an opportunity for clinicians in each organization to come to consensus on feedback they wish to give the work group and to consider changes needed across systems in their organization to implement the protocol.

All member organizations are encouraged to provide feedback on protocols; however, responding to review and comment is not a criterion for continued membership within the Institute for Clinical Systems Improvement (ICSI).

Document Approval

Each protocol is approved by the appropriate steering committee. There is a steering committee for Respiratory, Cardiovascular, Women's Health, and Preventive Services. The Committee for Evidence-based Practice approves guidelines, order sets, and protocols not associated with a particular category. The steering committees review and approve each protocol based on:

- Member comments have been addressed reasonably.
- There is sufficient reason to expect that members will use the protocol with minor modifications or adaptations.
- Within the knowledge of the reviewer, the recommendations in the protocol are consistent with other protocols, regulatory and safety requirements, or recognized authorities.
- When evidence for a particular step in the protocol has not been established, the work group identifies consensus statements that were developed based on community standard of practice and work group expert opinion.
- Either a review and comment by members has been carried out, or within the knowledge of the reviewer, the changes proposed are sufficiently familiar and sufficiently agreed upon by the users that new round of review is not needed.

Once the final draft copy of the protocol is developed, the document is sent to the ICSI members for review and comment.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is classified for selected recommendations (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate prevention of unintentionally retained foreign objects during vaginal deliveries

Potential Harms

Not stated

Qualifying Statements

Qualifying Statements

- This health care protocol is designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and is not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A health care protocol will rarely establish the only approach to a problem.
- This health care protocol should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients are urged to consult a health care professional regarding their own situation and any specific medical questions they may have.

Implementation of the Guideline

Description of Implementation Strategy

Once a guideline is approved for release, a member group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

Detailed measurement strategies are presented in the original guideline document to help close the gap between clinical practice and the guideline recommendations. Summaries of the measures are provided in the National Quality Measures Clearinghouse (NQMC).

Implementation Recommendations

Prior to implementation, it is important to consider current organizational infrastructure that address the following:

- System and process design
- Training and education
- Culture and the need to shift values, beliefs and behaviors of the organization

The following system changes were identified by the work group as key strategies for health care systems to incorporate in support of the implementation of this protocol.

1. The work group recommends that a standardized method, such as use of either a count worksheet or a white board, be used in Labor and Delivery to keep track of baseline, ongoing, and final counts. This method can then be used for final documentation or dictation in the medical record and/or submission into an electronic medical record.
2. The Labor and Delivery room needs to have a dedicated receptacle or location for all used sponges/soft goods in order to ensure accuracy in the count process. This must be in a location where staff can retrieve these items and not be co-mingled with the waste bucket at the foot of the bed.
3. The counting process must include a registered nurse and another person trained in the counting process.
4. Active support for the implementation of this protocol from administrative and medical leadership is essential.
5. Establish and/or maintain processes for ongoing training, measurement, and feedback for all involved staff.
6. Evaluation of count practices should include performance improvement audits. This is to ensure that count processes are being followed and not merely documented. Trends identified with audits can be used for ongoing training, measurement and feedback for all staff [X].
7. Red rules* should be established, followed by staff and physicians and supported by leadership (see below for specific red rules suggested for this protocol).

*Red rules are the few key rules created by the facility to prevent/address the specific actions that pose the highest level of consequence and risk to patients or staff. The intention is to develop solid habits around these rules so that they are followed consistently and accurately each time. Individual responsibility to adhere to each red rule is imperative to ensure a safe environment and consistent delivery of the desired care process.

Suggested red rules for Labor and Delivery:

1. All sponges and sharps will be counted for every vaginal delivery.
2. Only radiopaque sponges/soft goods will be present on Labor and Delivery trays or enter the delivery field.
3. If the count cannot be reconciled, imaging must be done.

Implementation Tools

Clinical Algorithm

Quality Measures

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Related NQMC Measures

Foreign object retention: percentage of unintentionally retained foreign objects during labor and delivery.

Foreign object retention: percentage of vaginal deliveries where a baseline count was conducted.

Foreign object retention: percentage of vaginal deliveries where a final count was conducted.

Foreign object retention: percentage of cases where final counts were not reconciled with baseline counts and imaging was performed.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Safety

Identifying Information and Availability

Bibliographic Source(s)

Institute for Clinical Systems Improvement (ICSI). Prevention of unintentionally retained foreign objects during vaginal deliveries. Health care protocol. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2012 Jan. 34 p. [24 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2008 Sep (revised 2012 Jan)

Guideline Developer(s)

Institute for Clinical Systems Improvement - Nonprofit Organization

Guideline Developer Comment

Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Community Medical Centers; Allina Medical Clinic; Aspen Medical Group; Baldwin Area Medical Center; Brown Clinic; Center for Diagnostic Imaging/Medical Scanning Consultants; CentraCare; Central Lakes Medical Clinic; Chippewa County – Montevideo Hospital & Clinic; Cuyuna Regional Medical Center; Essentia Health; Fairview Health Services; Family HealthServices Minnesota; Family Practice Medical Center; Fergus Falls Medical Clinic; Gillette Children's Specialty Healthcare; Grand Itasca Clinic and Hospital; Hamm Clinic; HealthEast Care System; HealthPartners Central Minnesota Clinics; HealthPartners Medical Group & Regions Hospital; Hennepin County Medical Center; Hennepin Faculty Associates; Howard Young Medical Center; Hudson Physicians; Hutchinson Area Health Care; Hutchinson Medical Center; Integrity Health Network; Lake Region Healthcare Corporation; Lakeview Clinic; Mankato Clinic; MAPS Medical Pain Clinics; Marshfield Clinic; Mayo Clinic; Mercy Hospital and Health Care Center; Midwest Spine Institute; Minnesota Association of Community Health Centers; Minnesota Gastroenterology; Multicare Associates; New Richmond Clinic; North Central Heart Institute; North Clinic; North Memorial Health Care; Northwest Family Physicians; Obstetrics and Gynecology Specialists; Olmsted Medical Center; Park Nicollet Health Services; Planned Parenthood Minnesota, North Dakota, South Dakota; Quello Clinic; Raiter Clinic; Rice Memorial Hospital; Ridgeview Medical Center; River Falls Medical Clinic; Riverwood Healthcare Center; South Lake Pediatrics; Southside Community Health Services; Stillwater Medical Group; University of Minnesota Physicians; Winona Health

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Source(s) of Funding

The following Minnesota health plans provide direct financial support: Blue Cross and Blue Shield of Minnesota, HealthPartners, Medica, Security Health Plan of Wisconsin, and UCare. In-kind support is provided by the Institute for Clinical Systems Improvement's (ICSI) members.

Guideline Committee

Patient Safety & Reliability Steering Committee

Composition of Group That Authored the Guideline

Work Group Members: Stephanie Doty, RN, MSN, MBA (*Work Group Leader*) (HealthPartners Regions Hospital) (Patient Safety & Quality); Kathleen Harder, PhD (University of Minnesota) (Human Factors Content Consultant); Carol Clark, RN, MSN (Fairview Health Services) (Nursing); Julie Thompson Larson, RN, BSN, MS (HealthPartners Regions Hospital) (Nursing); Cherida McCall, CNM (HealthPartners Medical Group) (Nurse Midwife); Douglas Creedon, MD, PhD (Mayo Clinic) (OB/GYN); Kari Retzer, RN (Institute for Clinical Systems Improvement) (Facilitator)

Financial Disclosures/Conflicts of Interest

In the interest of full disclosure, the Institute for Clinical Systems Improvement (ICSI) has adopted a policy of revealing relationships work group members have with companies that sell products or services that are relevant to this protocol topic. It is not assumed that these financial interests will have an adverse impact on content. They are simply noted here to fully inform users of the protocol.

Stephanie Doty, RN, holds personal stock with 3M.

Doug Creedon, MD, is the treasurer for the Minnesota section of the American Congress of Obstetrics and Gynecology.

No other work group members have potential conflicts of interest to disclose.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Institute for Clinical Systems Improvement (ICSI). Prevention of unintentionally retained foreign objects during vaginal deliveries. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2009 Nov. 30 p. [24 references]

Guideline Availability

Electronic copies: None available.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425.

Availability of Companion Documents

The following is available:

- Development and revision process for guidelines, order sets, and protocols. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2007 Jun. 5 p. Electronic copies: Available from the [Institute for Clinical Systems Improvement \(ICSI\) Web site](#)

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org ; e-mail: icsi.info@icsi.org

Patient Resources

None available

NGC Status

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